UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): September 30, 2020

Kadmon Holdings, Inc.
(Exact name of registrant as specified in its charter)

Delaware	**001-37841**	**27-3576929**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(I.R.S. Employer Identification No.)**

450 East 29th Street
New York, NY **10016**
(Address of principal executive offices) **(Zip Code)**

Registrant's telephone number, including area code (833) 900-5366

N/A
(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common stock, par value $0.001 per share	KDMN	The New York Stock Exchange

Indicate by check mark whether the registrant is an emerging growth company as defined in as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter). Emerging growth company x

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. x

Item 8.01 Other Events

On September 30, 2020, the Company issued a press release announcing the submission of a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) for belumosudil (KD025), the Company's Rho-associated coiled-coil kinase 2 (ROCK2) inhibitor, for the treatment of patients with chronic graft-versus-host disease (cGVHD).

The full text of the press release is attached to this Current Report on Form 8-K as Exhibit 99.1 and is incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press release, dated September 30, 2020, issued by Kadmon Holdings, Inc.

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Kadmon Holdings, Inc.

Date: September 30, 2020

/s/ Harlan W. Waksal
Harlan W. Waksal
President and Chief Executive Officer

Exhibit 99.1

Kadmon Announces Submission of New Drug Application to the U.S. FDA for Belumosudil in Patients with Chronic Graft-Versus-Host Disease

Application Being Reviewed Under FDA's Real-Time Oncology Review (RTOR) Pilot Program

NEW YORK, September 30, 2020 – Kadmon Holdings, Inc. (NYSE: KDMN) today announced the submission of a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) for belumosudil (KD025), the Company's Rho-associated coiled-coil kinase 2 (ROCK2) inhibitor, for the treatment of patients with chronic graft-versus-host disease (cGVHD).

"Today's NDA submission under the FDA's Real-Time Oncology Review pilot program marks an exciting milestone for Kadmon and for patients living with cGVHD," said Harlan W. Waksal, M.D., President and CEO of Kadmon. "We believe the robust and durable clinical trial results achieved with belumosudil demonstrate its potential to offer meaningful clinical benefit to cGVHD patients. We look forward to our continued dialogue with the FDA as we continue to make preparations for potential launch, if approved."

As previously reported, the NDA is being reviewed under the Real-Time Oncology Review (RTOR) pilot program, an initiative of the FDA's Oncology Center of Excellence. The RTOR program aims to explore a more efficient review process to ensure that safe and effective treatments are available to patients as early as possible.

The NDA submission is supported by positive data from ROCKstar (KD025-213), the Company's pivotal clinical trial evaluating belumosudil in 132 patients with cGVHD who have received two or more prior lines of systemic therapy. As previously reported, belumosudil achieved clinically meaningful and statistically significant Overall Response Rates (ORR) of 73% with 200 mg once daily and 74% with 200 mg twice daily. Responses were achieved across key patient subgroups and complete responses were observed in all organ systems. Belumosudil has been well tolerated and adverse events have been consistent with those expected in the patient population. Data from ROCKstar are expected to be presented at an upcoming medical meeting.

In October 2018, the FDA granted Breakthrough Therapy Designation to belumosudil for the treatment of patients with cGVHD after failure of two or more lines of systemic therapy.

About ROCKstar

ROCKstar (KD025-213) is an ongoing open-label trial of belumosudil (KD025) in patients with cGVHD who have received at least two prior lines of systemic therapy. Patients were randomized to receive belumosudil at 200 mg once daily or 200 mg twice daily, enrolling 66 patients per arm. The primary endpoint of the study is Overall Response Rate (ORR). The ORR endpoint was met at the interim analysis, conducted two months after completion of enrollment. At the study's primary analysis, conducted six months after completion of enrollment, belumosudil achieved ORRs of 73% and 74% in the respective arms. Data from ROCKstar are expected to be presented at an upcoming medical meeting.

About Belumosudil

Belumosudil (KD025) is a selective oral inhibitor of Rho-associated coiled-coil kinase 2 (ROCK2), a signaling pathway that modulates inflammatory response. The FDA has granted Breakthrough Therapy Designation to belumosudil for the treatment of patients with cGVHD after failure of two or more lines of systemic therapy. The FDA has also granted Orphan Drug Designation to belumosudil for the treatment of cGVHD. The belumosudil NDA is being reviewed under the FDA's Real-Time Oncology Review (RTOR) pilot program. Belumosudil is also being studied in an ongoing Phase 2 clinical trial in adults with diffuse cutaneous systemic sclerosis (KD025-209).

About cGVHD

cGVHD is a common and often fatal complication following hematopoietic stem cell transplantation. In cGVHD, transplanted immune cells (graft) attack the patient's cells (host), leading to inflammation and fibrosis in multiple tissues, including skin, mouth, eye, joints, liver, lung, esophagus and gastrointestinal tract. Approximately 14,000 patients in the United States are currently living with cGVHD.

About Kadmon

Kadmon is a clinical-stage biopharmaceutical company that discovers, develops and delivers transformative therapies for unmet medical needs. Our clinical pipeline includes treatments for immune and fibrotic diseases as well as immuno-oncology therapies.

Forward Looking Statements

This press release contains forward-looking statements. Such statements may be preceded by the words "may," "will," "should," "expects," "plans," "anticipates," "could," "intends," "targets," "projects," "contemplates," "believes," "estimates," "predicts," "potential" or "continue" or the negative of these terms or other similar expressions. Forward-looking statements involve known and unknown risks, uncertainties and other important factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. We believe that these factors include, but are not limited to, (i) the initiation, timing, progress and results of our preclinical studies and clinical trials, and our research and development programs; (ii) our ability to advance product candidates into, and successfully complete, clinical trials; (iii) the impact of the COVID-19 pandemic on our business, workforce, patients, collaborators and suppliers, including delays in anticipated timelines and milestones of our clinical trials and on various government agencies who we interact with and/or are governed by; (iv) our reliance on the success of our product candidates; (iv) the timing or likelihood of regulatory filings and approvals, especially in light of the COVID-19 pandemic; (v) our ability to expand our sales and marketing capabilities; (vi) our ability to expand our sales and marketing capabilities; (vii) the commercialization, pricing and reimbursement of our product candidates, if approved; (viii) the implementation of our business model, strategic plans for our business, product candidates and technology; (ix) the scope of protection we are able to establish and maintain for intellectual property rights covering our product candidates and technology; (x) our ability to operate our business without infringing the intellectual property rights and proprietary technology of third parties; (xi) costs associated with defending intellectual property infringement, product liability and other claims; (xii) regulatory developments in the United States, Europe, and other jurisdictions; (xiii) estimates of our expenses, future revenues, capital requirements and our needs for additional financing; (xiv) the potential benefits of strategic collaboration agreements and our ability to enter into strategic arrangements; (xv) our ability to maintain and establish collaborations; (xvi) the rate and degree of market acceptance of our product candidates, if approved; (xvii) developments relating to our competitors and our industry, including competing therapies; (xviii) our ability to effectively manage our anticipated growth; (xix) our ability to attract and retain qualified employees and key personnel; (xx) our expected use of cash and cash equivalents and other sources of liquidity; (xxi) the potential benefits of any of our product candidates being granted orphan drug designation; (xxii) the future trading price of the shares of our common stock and impact of securities analysts' reports on these prices; (xxiii) our ability to apply unused federal and state net operating loss carryforwards against future taxable income and/or (xxiv) other risks and uncertainties. More detailed information about the Company and the risk factors that may affect the realization of forward-looking statements is set forth in the Company's filings with the U.S. Securities and Exchange Commission (the "SEC"), including Kadmon's Annual Report on Form 10-K for the fiscal year ended December 31, 2019. Investors and security holders are urged to read these documents free of charge on the SEC's website at www.sec.gov. The Company assumes no obligation to publicly update or revise its forward-looking statements as a result of new information, future events or otherwise.

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